
Revised Test Plan
Zinc Dibutyldithiocarbamate (ZDBC)

CAS Registry Number 136-23-2

Rubber and Plastic Additives Panel
American Chemistry Council
December 2003

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List of Member Companies in the Rubber and Plastic Additives Panel

The Rubber and Plastic Additives Panel of the American Chemistry Council includes the following member companies: Alco Chemicals; Bayer Polymers LLC; Ciba Specialty Chemicals Corporation; Crompton Corporation; Eliokem, Inc.; Flexsys America L.P.; The Goodyear Tire & Rubber Company; The Lubrizol Corporation; Noveon, Inc.; and, R.T. Vanderbilt Company, Inc.

Summary

The member companies of the American Chemistry Council's Rubber and Plastic Additives (RAPA) Panel hereby submits this revised test plan and robust summaries of key studies for Zinc dibutyldithiocarbamate (ZDBC) to the High Production Volume (HPV) Chemical Challenge Program. The documents were revised taking comments received from the Environmental Protection Agency (EPA; dated June 20, 2003) and Environmental Defense (June 2, 2003) into account.

ZDBC is used as a primary accelerator in natural and synthetic rubbers. It also acts as an antioxidant in rubber-based adhesives. The characteristics that promote its use in rubber products include negligible water solubility, high organic/oil solubility, relatively low melting point and low vapor pressure. Existing data for this compound indicate that it is of low concern for mammalian toxicity but toxic to certain aquatic organisms. ZDBC is of moderate concern for skin irritation and allergic skin reaction.

The RAPA Panel concludes that there are sufficient data on ZDBC to meet the requirements of the HPV Program and no additional testing is recommended.

Aquatic Toxicology. ZDBC is toxic to water fleas (*Daphnia magna*) but not to fish. The 48-hr EC₅₀ for *Daphnia* is 0.74 ppm; the 96-hr LC₅₀ is 520 mg/l for rainbow trout and 880 mg/l for bluegill sunfish. No data are available on the toxicity of ZDBC to algae; however, the structural analog zinc dimethyldithiocarbamate (ZDMC; see below) is toxic to algae with a 96-hr EC₅₀ of 1.2 mg/l.

No adequate biodegradability or bioaccumulation studies have been located on ZDBC; however, these studies have been conducted on a close structural analogue, ZDMC. ZDMC is

inherently biodegradable, unstable in water (particularly under acidic conditions) and does not bioaccumulate. These data support the conclusion that there is little likelihood of ecological persistence or bioaccumulation for ZDMC and, by analogy, ZDBC.

Acceptable data for ZDBC are available on two of the three species commonly used for environmental toxicity studies. Acceptable data are available on a close structural analogue, ZDMC, for the third species and for biodegradation and stability in water. No additional ecotoxicity testing is proposed.

Acute Toxicity: The acute oral LD₅₀ for ZDBC is >5000 mg/kg; the acute dermal LD₅₀ is >2000 mg/kg. As acceptable data are available for two routes of exposure, no additional acute toxicity testing is proposed.

Mutagenicity: Bacterial reverse mutation assays and other *in vitro* and *in vivo* genetic toxicity studies have been conducted on ZDBC; results in all but one of these studies have been negative. The only study in which a weak positive result was reported was a human lymphocyte cytogenetics assay, and then only at doses which reduced cell division. Given the preponderance of negative assays using both *in vitro* and *in vivo* test systems there is sufficient basis to conclude that ZDBC is not mutagenic and that no additional mutagenicity testing is warranted.

Repeated Dose Toxicity: A 90-day study in rats, an 18-month carcinogenicity study in mice and a two-year chronic toxicity study in rats have been conducted on ZDBC. These data are acceptable to support characterization of the subchronic and chronic toxicity of ZDBC. No additional subchronic or chronic toxicity testing is proposed.

Reproductive and Developmental Toxicity: Reproductive and developmental toxicity studies have been conducted on ZDBC. The results of these studies show that ZDBC is not a selective or specific developmental or reproductive toxin. No additional reproductive or developmental testing is proposed.

Conclusion: The physical, chemical and toxicological properties of ZDBC have been considerably studied. An extensive and defensible hazard analysis can be made with available data; it is unlikely that additional studies would significantly change what is already known about this product. Therefore, the RAPA Panel concludes that there are sufficient data on ZDBC to meet the requirements of the HPV Program and recommends no additional testing.

Background Information: Manufacturing and Commercial Applications

Manufacturing

ZDBC has been manufactured worldwide for over 60 years. It is manufactured by batch rather than continuous process. ZDBC is manufactured by combining a secondary amine (di-n-butylamine) with carbon disulfide in alkaline aqueous solution, forming a water-soluble dithiocarbamate salt. The soluble salt is then converted to the insoluble zinc salt by reaction with zinc oxide.

Commercial Applications

The largest commercial use of ZDBC is as a general-purpose cure rate accelerator for natural and synthetic rubber vulcanization. It can be used as a primary accelerator in specialty applications and in latex (transparent goods). It also has antioxidant properties in rubber adhesive systems. Like other dithiocarbamates, ZDBC is typically used at 0.5 to 2 parts accelerator per every 100 parts of rubber (phr).

Worker/Consumer Exposure

The vast majority of ZDBC is used by the rubber industry, mostly by large industrial users as a component of their rubber compounds.

The rubber and plastics additives industry has a long safety record and sophisticated industrial users handle this material. It is available as pellets or powders; the powders are frequently treated with other materials to minimize dust generation. Most large industrial users also have mechanized materials handling systems, so exposure is generally minimal. The greatest potential for skin and inhalation exposure is at the packing station at the manufacturing site and, to a somewhat lesser degree during weighing activities at the customer site. Nuisance dust is the primary source of worker exposure.

Consumer exposure is considered minimal. Small amounts of ZDBC are used in rubber processing, and the materials themselves decompose or become bound in the rubber matrix during vulcanization. The most likely route of consumer exposure is skin contact from rubber or latex articles. Skin irritation, or possibly an allergic skin reaction may occur, but only in sensitive individuals subjected to prolonged and repeated exposure, especially under moist conditions. Because ZDBC is often used in the manufacture of medical exam gloves, there are recent published studies on extractability and allergic response potential on this and other dithiocarbamates.

ZDBC is regulated for use in food-contact applications by the U.S. Food and Drug Administration as follows:

21 CFR 178.2010, Antioxidants and/or stabilizers for polymers: (1) For use only at levels not to exceed 0.2% by weight of isobutylene-isoprene copolymers complying with 177.1420: provided that the finished copolymers contact food only of the types identified in 176.170, Table 1, under types V, VII, VIII and IX; and (2) At levels not to exceed 0.02% by weight of polypropylene polymers complying with 177.1520(c), item 1.1.

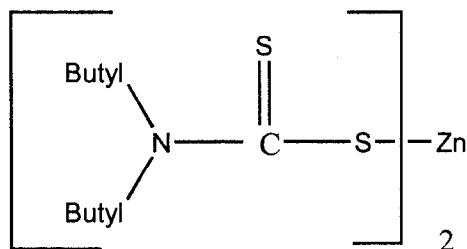
21 CFR 177.2600, Rubber articles intended for repeated use: As accelerator, not to exceed 1.5% by weight of rubber product.

21 CFR 177.1210, Closures with sealing gaskets for food containers: For use only in vulcanized natural or synthetic rubber gasket compositions, at levels not to exceed 0.8%.

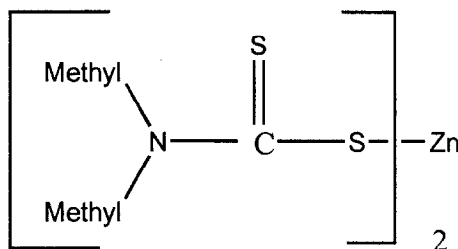
21 CFR 175.300, Resinous and polymeric coatings: For use in can end cements (sealing compounds used for sealing can ends only).

21 CFR 175.105, Components of Adhesives.

STRUCTURES



ZDBC



ZDMC

**ZINC DIBUTYLDITHIOCARBAMATE
(ZDBC)****Revised Test Plan**

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Physical-Chemical					
Melting Point	Boiling Point	Vapor Pressure	Partition Coefficient	Water Solubility	
A	A	Calc	Calc	Calc	
Environmental Fate					
Photodegradation	Stability in Water	Transport/ Distribution	Biodegradation		
Calc	SAR (ZDMC)	Calc	SAR (ZDMC)		
Ecotoxicity					
Acute Toxicity to Fish		Acute Toxicity to Aquatic Plants (e.g., Algae)		Acute Toxicity to Aquatic Invertebrates (e.g., Daphnia)	
A		SAR (ZDMC)		A	
Mammalian Toxicity					
Acute Toxicity	Bacterial Genetic Toxicity <i>In Vitro</i>	Mammalian Genetic Toxicity <i>In Vivo</i>	Repeat Dose Toxicity	Reproductive Toxicity	Developmental Toxicity
A	A	A	A	A	A

Legend	
Symbol	Description
Calc	Endpoint requirement fulfilled based on calculated data
A	Endpoint requirement fulfilled with adequate existing data
SAR (ZDMC)	Structure-Activity Relationship (zinc dimethyldithiocarbamate)